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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/585,546	03/02/2009	Marcin Krotkiewski	1914	5814
20676	7590	10/08/2010	EXAMINER	
ALFRED J MANGELS 4729 CORNELL ROAD CINCINNATI, OH 452412433			HOFFMAN, SUSAN COE	
			ART UNIT	PAPER NUMBER
			1655	
			MAIL DATE	DELIVERY MODE
			10/08/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/585,546	Applicant(s) KROTKIEWSKI, MARCIN	
	Examiner Susan Coe Hoffman	Art Unit 1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 August 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) 4,9-16 and 18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3,5-8 and 17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10 July 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>7/06</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Claims 1-18 are currently pending.

Election/Restrictions

2. Applicant's election with traverse of Group I, claims 1-8 and 17 and the extraction of claim 3 for the species in the reply filed on August 16, 2010 is acknowledged. The traversal is on the ground(s) that the two groups of invention do not lack unity because Maes (US 2008/0213202) does not show lack of unity because it is directed to a different invention than that claimed. Specifically, Maes is directed to a topical composition while the current invention is directed to a composition for treating obesity. This is not found persuasive because a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. The composition taught by Maes is capable of performing the intended use claimed by applicant. Thus, a difference in intended use is not sufficient to show that the two inventions have a linking special technical feature.

Applicant also argues that the two invention do not lack unity because the lack of unity was not found in the PCT application. However, national stage examination is not bound by the findings during the prosecution of the PCT. Thus, this argument is not persuasive.

In addition, applicant argues that the election of species requirement should be withdrawn because it would not be burdensome to search both species. However, establishment of burden is not required to find a lack of unity. Furthermore, a search of both species would be considered

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burdensome because each species requires separate consideration and search. Applicant also argues that the lack of unity does not apply to dependent claims if the independent claims avoid the prior art. However, the independent claims are not considered to avoid the prior art as discussed below.

The requirement is still deemed proper and is therefore made FINAL.

3. Claims 4, 9-16 and 18 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention and species, there being no allowable generic or linking claim.
4. Claims 1-3, 5-8 and 17 are examined on the merits.

Specification

5. The use of the trademark ssniff has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Objections

6. Claim 1 is objected to because of the following informalities: "catechins" is misspelled in line 5, "forskohlii" is misspelled in line 6, "flavonoids" is misspelled in line 10. Appropriate correction is required.

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7. Claims 2, 3, 5-8 and 17 are objected to because of the following informalities: the claims should read "The formulation" rather than "A formulation". Appropriate correction is required.

8. Claims 2 and 8 objected to because of the following informalities: the claims should read "further comprising" rather than "including" because additional ingredients are added to the composition of the parent claim. Appropriate correction is required.

9. Claims 5-7 and 17 are objected to because of the following informalities: "gallate" is misspelled. Appropriate correction is required.

10. Claim 8 objected to because of the following informalities: "laurylsulphate" should be "lauryl sulphate". Appropriate correction is required.

11. Claim 17 is objected to because of the following informalities: "catechins" is misspelled. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-3, 5-8 and 17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

12. Claim 1 is indefinite because the meaning of "vegetable extracts" in line 1 is unclear. The ingredients in the composition are not vegetables. Thus, it is unclear what "vegetable extracts" is referring to. Claim 1 is also indefinite because the definition of "associated metabolic syndrome" is unclear. In addition, claim 1 is indefinite because it is unclear if the

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percentages of catechins, diterpene forskolin, caffeine, caffeoylquinic acids, and flavonoids are by weight or volume.

13. Claim 2 is indefinite because it is unclear if the use of "vegetable extract" is intended to lend a structural characteristics to the white kidney bean extract.

14. Claim 3 is indefinite because it is unclear what temperatures are encompassed by "low" temperature. In addition, the Markush language in the claim is unclear. It is not clear what elements can be selected as alternatives. It is not clear if the claim intends to state two alternatives, specifically that the extract is obtained by water and ethyl acetate or water extraction at low temperature and under reduced pressure.

15. Claims 5-7 are indefinite because it is unclear if the EGCG percentages are by weight or volume.

16. Claim 8 is indefinite because the Markush language in the claim is unclear. It is not clear if the claim requires excipients, surfactants, and anti-caking agents or if the claim only requires one of these.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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17. Claims 1, 3, 5-8 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Liao (US 6,610,749), Majeed (US 5,804,596), Gow (US 7,279,184), de la Harpe (US 6,251,888), and BE 1009545.

Liao teaches using isolated EGCG extracted from green tea to reduce body weight. The composition contains ingredients such as cellulose and magnesium stearate. The EGCG is extracted using the method taught in Liao et al. (Biochem. Biophys. Res. Commun. (1995), vol. 214, pp. 833-838) which extracts the green tea using water and ethyl acetate (see "Materials", p. 834 of Liao et al. and columns 12 and 14 of the patent document). Isolated EGCG as taught by Liao is a green tea extract that is 100% EGCG; thus, the green tea extract meets the limitations of applicant's claims.

Majeed teaches using 1 to 40% forskohlin extracted from *Coleus forskohlii* to promote lean body mass.

Gow teaches using *Ilex paraguariensis* (yerba mate) extract to induce weight loss (see first full paragraph of column 23). The extract can contain 0.8% caffeine and 2.8% chlorogenic acid (3-Caffeoylquinic acid) (see Table 2, SFE CO₂ extract). This amount of caffeine and caffeoylquinic acid meets the limitations of applicant's claims.

De la Harpe teaches using *Betula pubescens* to increase lean body mass and reduce body fat (see claims 42 and 43). The composition also contains ingredients such as microcrystalline cellulose and magnesium stearate (see column 6, lines 2 and 23). *B. pubescens* is synonymous with *B. alba* (see www.botanical.com/botanical/mgmh/b/bircom43.html). The reference does not teach that the *B. pubescens* contains at most 3% flavonoids. However, BE '545 teaches using birch leaves to provide a slimming effect (see English abstract). Thus, an artisan of ordinary

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skill would reasonably expect that birch leaves would be useful in the composition taught by de la Harpe. This reasonable expectation of success would motivate the artisan to modify de la Harpe to include the use of birch leaves. Applicant's specification states that birch leaves contain 2-3% flavonoids (see paragraph 0009). Thus, the birch as suggested by de la Harpe and BE '545 meet the limitations of claim 1.

These references show that it was well known in the art at the time of the invention to use the claimed ingredients in compositions that would treat obesity. It is well known that it is prima facie obvious to combine two or more ingredients each of which is taught by the prior art to be useful for the same purpose in order to form a third composition which is useful for the same purpose. The idea for combining them flows logically from their having been used individually in the prior art.

Based on the disclosure by these references that these substances are used in compositions that would treat obesity, an artisan of ordinary skill would have a reasonable expectation that a combination of the substances would also be useful in creating compositions to treat obesity. Therefore, the artisan would have been motivated to combine the claimed ingredients into a single composition. No patentable invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients. See MPEP section 2144.06, *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980), *Ex parte Quadranti*, 25 USPQ2d 1071 (Bd. Pat. App. & Inter. 1992).

The references do not specifically teach adding the ingredients in the amounts claimed by applicant. The amount of a specific ingredient in a composition is clearly a result effective

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parameter that a person of ordinary skill in the art would routinely optimize. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). The references teach that each of the claimed ingredients is a pharmaceutically active ingredient. An artisan of ordinary skill would routinely modify the amount of pharmaceutically active ingredients based on the patient's age, weight, gender, and condition. Therefore, an artisan would have been motivated to modify the amount of each ingredient in the combination in order to formulate a product that best achieves the desired results set forth in the references. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of ingredient amount would have been obvious at the time of applicant's invention.

It is noted that applicant's specification contains data comparing the results of the individual ingredients in comparison with the combined ingredients. However, this data is not considered to render the claimed invention patentable based on unexpected results because the specification does not explain why the results shown are considered to be synergistic rather than additive as required by MPEP section 716.02 (a) or how the data are commensurate in scope with the broadly claimed invention (see MPEP section 716.02 (d)).

18. Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Liao (US 6,610,749), Majeed (US 5,804,596), Gow (US 7,279,184), de la Harpe (US 6,251,888), and BE 1009545 as applied to claims 1, 3, 5-8 and 17 above, and further in view of Chokshi (US 2003/0059403).

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The teachings of Liao, Majeed, Gow, de la Harpe, and BE '545 are discussed above. The references do not specifically teach using white kidney bean extract in the composition. Chokshi teaches using white kidney bean extract to induce weight loss (see paragraphs 45, 82 and claims). These references show that it was well known in the art at the time of the invention to use the claimed ingredients in compositions that would treat obesity. It is well known that it is prima facie obvious to combine two or more ingredients each of which is taught by the prior art to be useful for the same purpose in order to form a third composition which is useful for the same purpose. The idea for combining them flows logically from their having been used individually in the prior art.

Based on the disclosure by these references that these substances are used in compositions that would treat obesity, an artisan of ordinary skill would have a reasonable expectation that a combination of the substances would also be useful in creating compositions to treat obesity. Therefore, the artisan would have been motivated to combine the claimed ingredients into a single composition. No patentable invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients. See MPEP section 2144.06, *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980), *Ex parte Quadranti*, 25 USPQ2d 1071 (Bd. Pat. App. & Inter. 1992).

19. No claims are allowed.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Coe Hoffman whose telephone number is (571) 272-0963. The examiner can normally be reached on Monday-Thursday, 8:30-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Susan Coe Hoffman/
Primary Examiner, Art Unit 1655